



**Centers for Disease Control
and Prevention**
National Institute for Occupational
Safety and Health

Cons

ent to be in a Research Study

Health-related changes in cognitive performance

Environmental chamber component

Read Me First! – Important Key Information

- We're doing a study on 30 participants to find out how heat affects workers' concentration; this is important because heat exposure cause heat strain, which is the body's response to a heat load. Heat strain can lead to heat illness, which is a condition where the body cannot cool itself, leading to symptoms such as cramps, headaches, dizziness, and nausea or vomiting. Heat strain can also increase the risk of injuries, which is partly because of decreased concentration
- We would like to know if there is a way to use heart rate, body temperature, and air temperature/humidity to predict when workers' concentration starts to decrease
- Being in our study is 100% optional; there are no penalties for not signing up or for withdrawing
- Some health conditions may prevent you from being eligible for the study so you must complete a health questionnaire to determine if you can safely participate
- If you are over 40 years old or have diabetes or kidney disease, we will also collect a fingerstick blood sample to determine if you can safely participate
- Testing will take place over 3 days when you are off work, with 2 weeks in between testing days
- You will need to provide a urine sample on testing days to make sure you are hydrated
- You will need to swallow a pill that measures your body temperature, and you will wear a chest strap to monitor your temperature/heart rate
- You will be asked to do weighted squats alternating with stepping on and off of an 8-inch step at room temperature (70 °F and 40% humidity) and in hot conditions (100 °F and 80% humidity) until your temperature reaches a certain level, at which point you will take memory and attention tests
- On the second and third day, you will perform two rounds of exercise and memory/attention tests
- Testing will take about 3-6.5 hours a day depending on what part of the study you are in
- Your study results are confidential and will not be shared with your workplace or anyone else
- You will be compensated by check for your time at a rate of \$35/hour of study time and \$0.545 per mile travelled to and from the NIOSH testing building
- You will need to provide your Social Security Number for compensation purposes only
- We will work with you to set up testing on days that you are not working, so that the study will not interfere with work
- If your work is primarily seasonal, we will work with you to set up testing during the times of year where you're not busy working
- You will receive a report with your results, if you wish to receive them
- The main reason to participate is that we will gain important knowledge that will be used to help miners decrease the impact of heat strain in their jobs. The knowledge will also be used to develop safety guidelines for heat exposure in mines that may improve miners' safety in the future.

There are several reasons you may not want to participate in the study:

- You will be exercising at a moderate level, which may be uncomfortable, but you will be continuously monitored by a health professional, and we will stop testing if you have any issues or if you want to stop at any time
- You will need to swallow a temperature pill, and people who have known problems swallowing or GI

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<p>develop any symptoms</p> <ul style="list-style-type: none"> • There is a small chance that you could develop problems with your heart or injuries to your muscles while exercising in the heat, but you will be continuously monitored by a health professional, and we will stop testing if you develop any symptoms • Like with all studies, there is a small chance that your data could be compromised, but we have very high security standards and we will use coded IDs rather than names when collecting and storing your data 		
1	<p>Who is conducting the study?</p>	<p>The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC). Our website is: https://www.cdc.gov/niosh/index.htm</p>
2	<p>What is the purpose?</p>	<p>The purpose of this research is to study whether heat exposure affects worker performance and concentration. We would like to know if there is a way to use heart rate, temperature, and air temperature/humidity to predict when workers' ability to concentrate begins to decrease.</p>
3	<p>What will I do?</p>	<p>We will evaluate you in an environmental chamber on 3 separate days, separated by at least 2 weeks. An environmental chamber is a small, enclosed room where various air temperatures and humidity levels can be controlled in order to test the effects of the heat on different aspects of health and safety.</p> <p>Visit 1 Health screening, and who can't participant</p> <p>You will complete a health screening form to minimize testing safety risks. You will not be included in the study if you have any of the following conditions or report any of the following symptoms:</p> <ul style="list-style-type: none"> • History of coronary heart disease, arrhythmias, heart failure, valvular heart disease, stroke, and peripheral artery disease • Uncontrolled asthma (defined as daytime symptoms >2 times per week, limitations of exercise, nighttime symptoms at least once per week, or need for rescue treatment >2 times per week) • Pregnancy • Diabetes for more than 10 years or requiring the use of insulin • Chronic kidney disease stage 4 or 5 • Uncontrolled hyperthyroidism • Musculoskeletal injuries (injuries to muscles, joints, bones, ligaments, tendons, discs, or nerves; history of joint replacement or back surgery) in past 6 months resulting in time loss from work or other activities • History of heat stroke • History of seizures • Age 55 years or older • Chest discomfort or discomfort in the neck, jaw, or arms during exertion or while performing daily activities of living • Chest discomfort at rest • Shortness of breath at rest, with mild exertion, or that wakes you up at night and requires you to sit up in order to breathe better • Dizziness or fainting • Palpitations or fast heart rate • Unusual fatigue or shortness of breath with usual activities during the past 3 months • Crampy leg pain that occurs with exertion and is relieved with rest

- Medical conditions that prevent you from swallowing or passing the temperature pill (i.e., esophageal disorders, obstructive or hypomotility disorders of the gastrointestinal tract, previous gastrointestinal surgery, disorders of the gag reflex, having pacemaker or implantable cardioverter defibrillator, planning to have MRI within 2 days of study).
- Pregnancy

Physical examination

You will undergo a brief physical examination (heart and lung examination, blood pressure, heart rate measurement, height, and weight).

Fingerstick blood tests for certain participants

If you are 40 years old or older, we will prick your finger to obtain a few drops of blood, which will be used to test your cholesterol level. Information from the health screening, physical examination, and the cholesterol results will be entered into a computer program to estimate your 10-year risk of a cardiac event.

If you have diabetes, we will prick your finger to test your blood sugar and hemoglobin A1C. Hemoglobin A1C is a measure of blood sugar control over the past three months. If you have kidney disease, we will test your blood for serum electrolytes and kidney function.

Information from healthcare providers

On occasion, the NIOSH medical officer may request further information from your healthcare providers if it's not clear you can be in the study. You will need to sign a release of information form and provide the name and contact information of your health provider. The medical officer will call the health provider and will request only the needed medical information. All conversations between your health provider and the NIOSH medical officer will be documented by the medical officer, and this information will be confidential and maintained in a locked cabinet.

Equipment set-up

Directly after the health questionnaire, you will swallow a pill that will be used to monitor your temperature. Then you will take the 2 memory and attention tests to get a baseline level. These tests will be on a tablet or computer.

Cognitive tests

After the baseline attention tests are done, you will go to the environmental chamber for a physical baseline test. The chamber will be at room temperature. You will exercise for a total of 20 minutes, alternating between 1 minute of strength exercise and 1 minute of cardio exercise. For the strength exercise, you will be doing squat exercises with 10-pound weights in each hand. For the cardio exercise, you will be stepping up and back down on a low step with 5-pound weights in each hand. After exercising for 20 minutes, you will take the memory and attention tests again.

The total time to complete these steps the first day is approximately 3 to 4 hours.

Visit 2 and 3

Visit 2 and 3 will be the same, and visits will be separated by at least two weeks

		<p>from each other.</p> <p>Equipment set-up and brief health screening You will swallow the temperature pill as soon as you arrive at the laboratory. We will give you a health screening questionnaire to determine if you have had recent health issues that could be worsened by the study testing. The medical officer will check your heart rate and blood pressure and you will provide a urine sample so we can make sure you are hydrated. We will not test for anything else and will promptly discard the urine. Then, you will do the memory and attention tests to get a baseline level.</p> <p>Testing in chamber – exercise Each study day will consist of two rounds of exercises and memory tests in the chamber. In one of the rounds, you will exercise until you reach a temperature of 100.4 °F, and in the other round you will exercise until you reach a temperature of 101.3 °F. You will be randomly placed into one of two groups. The group that you are assigned to will determine which order you reach 100.4 °F and 101.3 °F (i.e., some people will be assigned to reach 100.4 °F in round one and 101.3 °F in round two; other people will be assigned to reach 100.4 °F in round two and 101.3 °F in round one).</p> <p>The exercise on visits 2 and 3 will be the same as the exercise you did on visit 1 (with alternating cycles of strength and cardio exercises as before), but the chamber will be set to 100 °F with 80% relative humidity instead of room temperature. You will do 20 minutes of the exercises, followed by 10 minutes of seated rest, followed by 10 minutes of the same alternating exercise cycles, followed by 10 minutes of seated rest, followed by 5 minutes of the same alternating exercise cycles.</p> <p>Testing in chamber – cognitive tests As soon as your temperature reaches the temperature we need, you will stop exercise and begin the memory and attention tests. The memory and attention tests should take about 11 minutes.</p> <p>You will rest at least 30 minutes between the rounds. Each round should take 30-75 minutes, depending on how long it takes your temperature to reach the temperature we need. After you leave the chamber between rounds, we will test your urine again to make sure you are hydrated.</p> <p>The total time for each study day is about 5 ½-6 hours.</p>
4	<p>When, where, for how long will I be needed?</p>	<p>The study will be performed outside of your working hours and in the off- season (for seasonal workers). The study must be done at the Spokane Research Laboratory in Spokane, WA. We estimate that the study activities will take a total of 14 to 16 hours in total over 3 days of testing. Each study day must be separated by at least 2 weeks.</p>
5	<p>Are there any risks?</p>	<p>Heart problems During the exercise test, you will exercise at a moderate level of physical activity. Your blood pressure, heart rate, and body temperature will increase during the testing. Changes such as abnormal blood pressure, fainting, or irregular heartbeats can occur during exercise. In rare cases, serious events such</p>

as heart attack, stroke, or death may occur, but these occur in less than 6 people per 10,000 people who perform exercise tests.

To minimize these risks, a medical professional will screen you for risks of cardiovascular disease prior to enrolling in the study and prior to each study day to minimize these risks. Persons at higher risk of cardiovascular disease will not be allowed to participate. A medical officer experienced in patient assessment and care will monitor you at all times during the study. Emergency equipment such as an AED (automated external defibrillator) and NIOSH personnel trained in CPR and first aid are available to deal with situations that might arise. You will also be asked to inform investigators any time you feel unable to continue the test or if you develop any symptoms, especially of chest pain, shortness of breath, dizziness, focal numbness or weakness, nausea, or vomiting.

Heat illness (body overheating)

Another risk is the possibility of your body overheating. Guidelines from international and national organizations such as NIOSH, WHO, and ACGIH recommend that unacclimatized workers' core body temperatures should not exceed 100.4 °F to prevent heat illness. Because you will be exercising in hot conditions, your core body temperature will rise above the temperatures recommended by these organizations. It is important that we raise your temperature above recommended limits so that we can study what happens to your attention and memory at these levels, in order to develop ways to decrease the risk of heat strain causing injuries among miners. It is possible that you could develop symptoms of heat illness such as nausea, vomiting, muscle cramps, or dizziness when your body's temperature is elevated, and these symptoms could progress to the point you need to go to the hospital. This risk is low (<1-4 per million persons) because we will monitor you closely and stop the test if you develop any symptoms. We will continuously monitor your core body temperature and heart rate as they increase. We will repeatedly ask you if you have any symptoms of headache, nausea, vomiting, muscle cramps, or dizziness. You will be instructed to inform us as soon as you notice any new symptom at all. We will stop the testing if your core body temperature remains above 102.2 °F for longer than 2 minutes and/or your heart rate is too high. You may stop testing at any time before that if you feel you cannot or do not want to continue. After leaving the chamber, you will remain on a cot resting until your temperature and heart rate have dropped sufficiently. We will provide you with cold fluids after you complete a testing session. If you suffer from heat illness during the testing, we will treat you with cold packs or ice packs, iced towels, fluids, and fans, and will monitor you for the need for emergency medical care services.

Capsule ingestion

Risks associated with the ingestible temperature pills are low but involve inability to swallow the capsule in persons with esophageal disorders; inability to pass the capsules in persons with obstructive or hypomotility disorders of the gastrointestinal tract, previous gastrointestinal surgery, or swallowing/gag reflex disorders; or interference of the capsule with pacemakers, implantable cardioverter defibrillators, or MRI scanning. Participants will not necessarily know when they have passed the temperature capsule, because they will not always be able to see the capsule in their stool. They will be instructed to call their health provider if they have constipation after test days, along with any of the following symptoms: substantial bloating, feeling like they need to pass stool but are unable to do so, nausea or vomiting, inability to pass gas, or abdominal pain. It is not possible to predict when someone will pass the pill because it

		<p>depends on their usual bowel habits (i.e., someone who has a bowel movement once a day or more frequently will probably pass the pill within 24 hours, whereas someone who has bowel movements every 2-3 days will pass the pill more slowly). To minimize the risk, we will screen you for bowel disorders that could prevent you from passing the capsule.</p> <p>Musculoskeletal pain or injuries</p> <p>There is a moderate risk of musculoskeletal injuries and soreness from the squats with weights or step-ups with weights. To minimize this risk, we will instruct you in proper squat techniques and will monitor you to ensure proper form.</p> <p>Loss of confidentiality of data</p> <p>Another risk of participating is a possible loss of confidentiality of your records if an unauthorized person accesses the data. This risk is low because NIOSH takes your privacy seriously and every care will be taken to keep your information safe. To minimize this risk, all questionnaires will be identified with unique identifiers rather than personally identifiable information (PII), and the key (with names and unique identifiers) will be maintained on paper in a locked cabinet in a secure NIOSH facility. You will not be identified by name to other researchers and study results will be shared as a group. After data collection for all participants has been completed and data are checked for completeness and quality, the link between your name and unique identifier will be destroyed.</p> <p>Cognitive tests</p> <p>No risks are anticipated from taking the memory and attention tests.</p> <p>Receiving study results</p> <p>You have the option to receive your study results. The medical officer will review them with you and identify any potential results for you to review with your personal care physician. If you choose to follow-up with your primary care physician, any incurred cost is your responsibility. Participation also poses some risk of over-identification of health conditions (e.g., elevated blood pressure) that do not in fact warrant medical attention, which could indirectly result in complications from testing and subsequent treatment rendered by outside healthcare providers in response to health screening results. In addition, this overdiagnosis could result in psychological stress. However, NIOSH does not plan to diagnose any health conditions.</p> <p>This examination is intended to collect health measures for research. It is not intended to provide information on which workers might have a higher risk for heat strain.</p>
6	<p>Is my participation voluntary?</p>	<p>Your participation in the study is voluntary. You may choose to answer any or all questions. You may decline to participate or drop out at any time, for any reason, with no penalty or loss of benefits to which you are otherwise entitled. However, answering all questions on the health questionnaire is required so we have all the information necessary to determine whether you can safely participate. If you decline to answer these questions, you will be unable to participate further, but there will be no other consequences to you. You may drop out any time for any reason without consequences to you from NIOSH or your work supervisor.</p> <p>Testing will be stopped at any time you wish to stop or if any of the following criteria are met:</p>

		<ul style="list-style-type: none"> You are too tired to continue You have any symptom related to heat exposure or exercise (e.g. lightheadedness, dizziness, chest pain, shortness of breath, nausea/vomiting, muscle or joint weakness, pain, or cramping) Your core body temperature is above 102.2 °F for longer than 2 minutes Your heart rate is higher than 95% of your maximal heart rate for more than a minute
7	<p>What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?</p>	<p>If you suffer from heat illness during the testing, we will treat you with cold packs or ice packs, iced towels, fluids, and fans, and will monitor you for the need for emergency medical care services. We will only call 911 if your symptoms worsen or do not resolve within 30 minutes.</p> <p>NIOSH will summon emergency medical aid by calling 911. If NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of research-related injuries will be provided by NIOSH, the CDC, or the Federal Government. However, if you believe NIOSH has been negligent in conducting the research study and you believe you have suffered a harm as a result, you have the right to pursue a legal remedy under the Federal Tort Claims Act (28 U.S.C. §§ 2671-2680 and 28 U.S.C. § 1346(b)). To learn more about how to file a Federal Tort claim, call the General Law Division of the HHS Office of the General Counsel at (202) 619- 2155 or go to https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html.</p>
8	<p>Will I be reimbursed or paid?</p>	<p>You will be compensated for travel (\$0.545 per mile) and time (\$35 per hour). If you are not accepted into this study because of health screening results, you will be compensated only for the time you spent for health screening (i.e. health questionnaire and physical examination). If you are accepted into the study, you will be compensated for the time you spent on the health screening, physical examination, and memory and attention tests. If you are not accepted into the study, you will be compensated for the time that you spend in screening activities. Compensation time on study days will commence upon arrival to the NIOSH facility and end when participants leave the facility (i.e. participants will be compensated for mileage but not travel time). Partial hours will be compensated by rounding to the nearest half hour and paying \$17.50 for that half hour. For example, if you spend 4 hours and 10 minutes on the study during one of the study days, we will round to 4 ½ hours. For the compensation process, you will need to provide your Social Security Number.</p>
9	<p>Are there other benefits?</p>	<p>Participants will receive no direct benefits from participation in the study.</p> <p>The medical officer will review your health screening form and identify issues that would benefit from medical evaluation and treatment and will discuss these findings with you. Early treatment of some health conditions may prevent complications. You will also receive written results of your blood pressure, cholesterol, and body mass index, along with information explaining the results. The medical officer will also explain your results to you.</p>

		Knowledge gained from this study will help NIOSH and mines to prevent heat strain among all workers.
10	What alternative procedures might benefit me?	No alternative procedures are available for this study.
11	Will my personal information be kept private?	<p>Your information will be kept private and secure. After all questionnaire and measurement information has been recorded and verified electronically, all forms containing participant names will be destroyed according to CDC policy. We will not use your contact information for any other purpose and will destroy it after the study has been completed. Only CDC researchers and research partners will be able to access your information.</p> <p>This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.</p> <p>HHS System of Records Notices (SORNs) are required for studies in which the Privacy Act is applicable. As required by The Privacy Act, HHS publishes SORNs to provide public notice of the records it maintains about individuals. Each SORN describes the types of information contained in the records, the legal authority for collecting and maintaining the records, how the records are used within HHS, and the purposes for which HHS may disclose the records to non- HHS parties without the individual record subject's consent. The SORN that covers this study confidentiality is 09-20-0117 Medical and Test Record Results of Individuals Involved in NIOSH Laboratory Studies.</p> <p>Information or biospecimens (e.g. urine, blood) collected as part of this research will not be used or distributed for future research studies.</p>
12	Will I or anyone else receive study results?	<p>We will provide you a copy of your temperatures as well as your memory and attention test results at the end of the study, if you wish to receive them. These results are for your interest only but are not clinically relevant. There are no "abnormal" or "normal" results for the memory and attention tests, so you will not be able to make changes to your work tasks after reviewing the results. We will provide you with your maximum temperature during each study day. This information tells you how high your temperature gets when you're in hot and humid conditions. These temperatures are not clinically relevant, meaning that there is nothing a health provider would do with them. If you receive</p>

		<p>fingerstick blood tests (depending on your age or underlying health conditions), you will have the option of receiving these results. These results are clinically relevant; they can provide you with information on your risk for heart disease and could be shared with your health provider for further evaluation and confirmation. We will mail the results to you after verifying with you that we have your correct address. You will have the option of calling the medical officer with any questions. We will also present aggregated results during a group debriefing session for all participants who are interested in attending. We will ensure that aggregated results cannot be used to identify the results of any individual participant. You may opt out of receiving results.</p>
13	Will my personal information or samples collected from me be used in other research?	<p>No. All urine samples and fingerstick blood samples collected will be discarded and will not be used for other research.</p>
14	Who can I talk to if I have more questions?	<p>For questions about the research study, contact the principal investigator, Kristin Yeoman at vij6@cdc.gov or 509-354-8067.</p> <p>For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591.</p>
15	Your signature	<p>The study was explained to me. My questions were answered. I agree to be in the study.</p> <p>_____</p> <p>Printed name of participant</p> <p>_____</p> <p>Participant signature Date</p> <p>I have accurately described this study to the participant.</p> <p>_____</p> <p>NIOSH representative signature Date</p>

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Additional consent

No, do not send me the results of my core body temperature

Yes, please send me the results of my core body temperature

by email

by postal mail

No, do not send me the results of my memory and attention tests

Yes, please send me the results of my memory and attention tests

by email

by postal mail

No, do not provide me with the results of my fingerstick blood tests

Yes, please provide me with the results of my fingerstick blood tests at the time of my health screening

Printed name of participant

Participant signature

Date

Participant email

Participant mailing address (street address) (apt.#)

(city, state & zip code)